

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Compleat If Known</b>		
			Application Number	Filed Herewith	
			Filing Date	December 11, 2002	
			First Named Inventor	German, Michael S.	
			Art Unit	Unassigned	
Examiner Name	Unassigned				
Sheet	1	of	3	Attorney Docket Number	023070-138122US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
1.P.	AA	US-5,166,320	11/24/1992	Wu, et al.	
	AB	US-5,670,347	09/23/1997	Gopal	
	AC	US-5,766,899	06/16/1998	Kuo, et al.	
	AD	US-5,792,751	08/11/1998	Ledley, et al.	
	AE	US-5,827,703	10/27/1998	Debs, et al.	
	AF	US-5,858,351	01/12/1999	Podsakoff, et al.	
	AG	US-6,083,905	07/04/2000	Voorberg, et al.	
	AH	US-6,093,392	07/25/2000	High, et al.	
	AI	US-6,177,554	01/23/2001	Woo, et al.	
1.P.	AJ	US-6,265,387	07/24/2001	Wolff, et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>				
1.P.	AK	PCT	WO 91/06309 A1	05/16/1991	Univ. Vanderbilt		<input type="checkbox"/>
	AL	PCT	WO 93/19660 A1	10/14/1993	Baylor College Medicine		<input type="checkbox"/>
	AM	PCT	WO 94/29471 A1	12/22/1994	Genetic Therapy Inc.		<input type="checkbox"/>
	AN	PCT	WO 95/02698	01/26/1995	Life Technologies Inc.		<input type="checkbox"/>
1.P.	AO	PCT	WO 96/30050	10/03/1996	Univ. California		<input type="checkbox"/>

Examiner Signature	<i>Deanna P. T. M.</i>	Date Considered	10/12/08
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 801.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete If Known</b>			
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		First Named Inventor	German, Michael S.		
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Sheet	2	of	3	Attorney Docket Number	023070-138122US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
I.P.	AP	ABEMDROTH, et al., AN96126219, (1996).	
	AQ	ANDERSON, et al., "Human gene therapy," <i>Nature</i> , Vol. 392, pp. 25-30, (1998).	
	AR	<i>Biotechnology</i> , Vol. 10, pp. 132-136, (1992).	
	AS	BRUINSMA, et al., "Towards a new gene transfer system: Shock wave-mediated DNA transfer," pp. 102-103, (1994).	
	AT	GUMUCIO, D. L., et al., "Concerted Evolution of Human Amylase Genes," <i>Mol. Cell. Biol.</i> , Vol. 8, No. 3, pp. 1197-1205, (1988).	
	AU	HATZOGLOU, M., et al., "Hepatic Gene Transfer in Animals Using Retroviruses Containing the Promoter from the Gene for Phosphoenolpyruvate Carboxykinase," <i>J. Biol. Chem.</i> , Vol. 265, pp.17285-17293, (October 1990).	
	AV	HICKMAN, et al., "Gene expression following direct injection of DNA into liver," pp. 1477-1483, (1994).	
	AW	HICKMAN, et al., "Therapeutic response produced by direct," p. 241, (1994).	
	AX	MELLITUS, <i>Journal of Endocrinology</i> , Vol. 143, pp. 339-343, (1994).	
	AY	OSBORN, L., et al., "Insulin Response of a Hybrid Amylase/CAT Gene in Transgenic Mice," <i>J. Biol. Chem.</i> , Vol. 263, No. 32, pp. 16519-16522, (November 1988).	
	AZ	PONDER, AN2000103902, (1999).	
	BA	SCHMID, R., et al., "Liposome Mediated in vivo Transfer Into Different Tissues of the Gastrointestinal Tract," <i>Zeitschrift fuer Gastroenterologie</i> , Vol. 32, No. 12, pp. 665-670, (1994).	
	BB	SOSA-PINEDA, et al., "The pax4 gene is essential for differentiation of insulin-producing beta cells in the mammalian pancreas," <i>Nature</i> , Vol. 386, pp. 399-402, (1997).	
	BC	TRIPATHY, S.K., et al., "Stable delivery of physiologic levels of recombinant erythropoietin to the systemic circulation by intramuscular injection of replication-defective adenovirus," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91, pp.11557-11561, (November 1994).	
I.P.	BD	VALERA, et al., "Regulated Expression of Human Insulin in the Liver of Transgenic Mice Corrects Diabetic Alterations," <i>Research Communications, US, FED. OF AMERICA SOC. FOR EXPERIMENTAL BIOLOGY</i> , BETHESDA, MD, (April 1994), Vol. 8., No. 8., pg. 440, paragraph 4, pg. 441, paragraph 2.	

Examiner Signature	<i>Deann R. Ma</i>	Date Considered	<i>10/12/02</i>
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1.P.	BE	VERMA, et al., "Gene therapy-promises, problems and prospects," <i>Nature</i> , Vol. 389, pp. 239-242, (1997).	
1.P.	BF	YAMADA, et al., "In vivo identification of a negative regulatory element in the mouse rennin gene using direct gene transfer," <i>J. Clin. Invest.</i> , Vol. 96, pp. 1230-1237, (1995).	

Examiner Signature	<i>Thomas P. No</i>	Date Considered	10/12/08
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# INFORMATION DISCLOSURE CITATION

Form PTO-1449 (Modified)

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Applicant: GERMAN, Michael S.

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## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
1.P.	AA	4,394,443	07/19/83	Weissman, et al.	435	6	12/18/80
	AB	4,683,195	07/28/87	Mollis, et al.	435	6	02/07/86
	AC	4,683,202	07/28/87	Mollis	435	91	10/25/85
	AD	4,703,008	10/27/87	Lin	C12N	5/00	11/30/84
	AE	4,861,719	08/29/89	Miller, et al.	435	236	04/25/86
	AF	5,139,941	08/18/92	Muzyczka, et al.	435	172.3	10/25/91
	AG	5,219,740	06/15/93	Miller, et al.	435	69.6	02/13/87
	AH	5,240,846	08/31/93	Collins, et al.	435	240.1	09/18/90
	AI	5,292,662	03/08/94	Sandmeyer	435	320.1	06/08/92
	AJ	5,328,470	07/12/94	Nabel, et al.	604	101	07/26/91
	AK	5,356,806	10/18/94	Harris, et al.	435	240.2	04/13/92
	AL	5,399,346	03/21/95	Anderson, et al.	424	93.21	03/30/94
	AM	5,589,466	12/31/96	Felgner, et al.	A61K	48/00	01/26/95
1.P.	AN	6,004,944	12/21/99	Rothman, et al.	A61K	48/00	10/02/97

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
1.P.	AO	WO 94/26915	11/24/94	PCT	C12N	15/86		XX
1.P.	AP	WO 99/17610	11/15/99	PCT	C12N	13/00		XX

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

1.P.	AQ	Amsterdam, et al., "Studies on Dispersed Pancreatic Exocrine Cells," <i>J. Cell. Biol.</i> , 63:1057-1073 (1974).						
1.P.	AR	Avery, et al., "Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types," <i>J. Exp. Med.</i> , 174:137-158 (1994).						
1.P.	AS	Baum, "Advances in Salivary and Soft Tissue Management," <i>JADA</i> , 125:26S-30S (1994).						

EXAMINER <i>Deane PDM</i>	DATE CONSIDERED <i>10/12/05</i>
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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

1. P.	AT	Boshart, et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <i>Cell</i> , 41:521-520 (1985).
	AU	Brody, et al., "Adenovirus-Mediated <i>In Vivo</i> Gene Transfer," <i>NY Acad. Sci.</i> , 716:90-101 (1994).
	AV	Cockell, et al., "Identification of a Cell-Specific DNA-Binding Activity that Interacts with a Transcriptional Activator of Genes Expressed in the Acinar Pancreas," <i>Mol. Cell. Biol.</i> , 9:2464-2476 (1989).
	AW	Coghlan, "Gene Dream Fades Away," <i>New Scientist</i> , (Nov. 1995):14-15.
	AX	Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> , 270:404-410 (1995).
	AY	Elango, et al., "Molecular Cloning and Characterization of Six Genes, Determination of Gene Order and Intergenic Sequences and Leader Sequence of Mumps Virus," <i>J. Gen. Virol.</i> , 69:2893-2900 (1988).
	AZ	Felgner, et al., "Lipofection: A Highly Efficient, Lipid-Mediated DNA-Transfection Procedure," <i>Proc. Nat'l. Acad. Sci. USA</i> , 84:7413-7417 (1987).
	BA	Fynan, et al., "DNA Vaccines: Protective Immunizations by Parenteral, Mucosal, and Gene-Gun Inoculations," <i>Proc. Nat'l. Acad. Sci. USA</i> , 90:11478-11482 (1993).
	BB	Gerrard, et al., "Towards Gene Therapy for Haemophilia B Using Primary Human Keratinocytes," <i>Nat. Genet.</i> , 3:180 (1993).
	BC	Gitschier, et al., "Characterization of the Human Factor VIII Gene," <i>Nature</i> , 312:326-330 (1984).
	BD	Gorman, et al., "The Rous Sarcoma Virus Long Terminal Repeat is a Strong Promoter when Introduced into a Variety of Eukaryotic Cells by DNA-Mediated Transfection," <i>Proc. Nat'l. Acad. Sci. USA</i> , 79:6777-6781 (1982).
	BE	Grendell, et al., "Effect of Changes in Circulating Amylase Levels on Amylase Output in Bile," <i>The American Physiological Society</i> , G54-G59 (1982).
	BF	Groot, et al., "The Human $\alpha$ -Amylase Multigene Family Consists of Haplotypes with Variable Numbers of Genes," <i>Genomics</i> , 5:29-42 (1989).
	BG	Gunzberg, et al., "Virus vector design in gene therapy," <i>Molecular Medicine Today</i> 410-417 (1995).
	BH	Hagenbuchle, et al., "Expression of Mausy Amy-2 <sup>+</sup> Alpha-Amylase Genes is Regulated by Strong Pancreas-Specific Promoters," <i>J. Mol. Biol.</i> , 185:285-293 (1985).
1. P.	BI	Hewitt, et al., "Human Gastric Intrinsic Factor: Characterization of cDNA and Genomic Clones and Localization to Human Chromosome 11," <i>Genomics</i> , 10:432-440 (1991).

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

1.0	BJ	Jones, et al., "A Salivary Amylase Transgene is Efficiently Expressed in Liver but Not in Parotid Gland of Transgenic Mice," <i>Nucleic Acid Res.</i> , 17(6):6613-6623 (1989).
	BK	Korman, et al., "Expression of Human Class II Major Histocompatibility Complex Antigens Using Retrovirus Vectors," <i>Proc. Nat'l. Acad. Sci. USA</i> , 84:2150-2154 (1987).
	BL	Kozarsky, et al., "Adenovirus-Mediated Correction of the Genetic Defect in Hepatocytes from Patients with Familial Hypercholesterolemia," <i>Somat. Cell Mol. Genet.</i> , 19(5):449-458 (1993).
	BM	Kwano, et al., "Complete Nucleotide Sequence of the Matrix Gene of Human Parainfluenza Typ 2 Virus and Expression of the M Protein in Bacteria," <i>Viol.</i> , 179:857-861 (1990).
	BN	Ledley, "Nonviral gene therapy: the promise of genes as pharmaceutical products," <i>Human Gene Therapy</i> , 6:1129-1144 (1995).
	BO	Lowry, et al., "Protein Measurement with the Folin Phenol Reagent," <i>J. Biol. Chem.</i> , 193:265-275 (1951).
	BP	Maeda, et al., "Adenovirus-Mediated Transfer of Human Lipase Complementary DNA to the Gallbladder," <i>Gastroenterology</i> , 106:1638-1644 (1994).
	BQ	Marshall, et al., "Less Hype, Mor Biology Needed for Gene Therapy," <i>Science</i> , 270:1751 (1995).
	BR	Marshall, "Gene Therapy's Growing Pains," <i>Science</i> , 269(5227):1050 (1995).
	BS	Martial, et al., "Human Growth Hormone: Complementary DNA Cloning and Expression in Bacteria," <i>Biotechnology</i> , 24:293-298 (1992).
	BT	Mastrangeli, et al., "Direct In Vivo Adenovirus-Mediated Gene Transfer to Salivary Glands," <i>Am. J. Physiol.</i> , 266:(6, part 1):G1146-55 (1994).
	BU	Mastrangelo, et al., "Gene Therapy for Human Cancer: An Essay for Clinicians," <i>Seminars in Oncology</i> , 23:4-21 (1996).
	BV	Miller, et al., "Targeted Vectors for Gene Therapy," <i>FASEB J.</i> , 9(2):190-199 (1995).
	BW	Miyasaka, et al., "Endocrine Secretion of $\alpha$ -Amylase by the Process by the Pancreas," <i>American Physiological Society</i> , G170-G175 (1981).
	BX	Morgan, et al., "Expression of an Exogenous Growth Hormone Gene by Transplantable Human Epidermal Cells," <i>Science</i> , 237:1476-1479 (1987).
	BY	Morsy, et al., "Progress Toward Human Gene Therapy," <i>JAMA</i> , 270:2338-2345 (1993).
	BZ	Mulligan, "The Basic Science of Gene Therapy," <i>Science</i> , 260:926-932 (1993).
	CA	Newgard, et al., "Molecular Engineering of the Pancreatic $\beta$ -Cell," <i>J. Lab. Clin. Med.</i> , 122(4):356-363 (1993).
1.0	CB	Orkin, et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," December 7, 1995.

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

J.P.	CC	Pittet, et al., "Mouse Alpha-Amylase Loci, Amy-2 <sup>a</sup> and Amy-1 <sup>a</sup> , are Closely Linked," <i>J. Mol. Biol.</i> , 182:359-365 (1985).
	CD	Ramakrishna, et al., "Gene Therapy for Exocrine Pancreatic Insufficiency," <i>Gastroenterology</i> , 106(6):1711-1713 (1994).
	CE	Robins, et al., "Retrotransposons sand the Evolution of Mammalian Gene Expression," <i>Genetica</i> , 86:191-201 (1992).
	CF	Rosenfeld, et al., "Adenovirus-Mediated Transfer of a Recombinant $\alpha$ -Antitrypsin Gene to th Lung Epithelium In Vivo," <i>Science</i> , 252:431-434 (1991).
	CG	Rosenfeld, et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium," <i>Cell</i> , 68:143-155 (1992).
	CH	Samara, et al., "Molecular Biology and Therapy of Disease," <i>The American Journal of Surgery</i> , 165:720-727 (1993).
	CI	Samuelson, et al., "Expression of the Human Amylase Genes: Recent Origin of a Salivary Amylase Promoter from an Actin Pseudogene," <i>Nucleic Acids Res.</i> , 16:8261-8276 (1988).
	CJ	Schibler, et al., "Structural Arrangement of and Tissue-Specific Expression of the Two Murine Alpha-Amylase Loci Amy-1 and Amy-2," <i>Oxf. Surv. Eukaryot. Genes</i> , 3:210-234 (1986).
	CK	Sierra, et al., "Different Tissue-Specific Expression of the Amylase Gene Amy-I in Mice and Rats," <i>Mol. Cell. Biol.</i> , 6(11):4067-4076 (1986).
	CL	Stewart, et al., "Insulin Delivery by Somatic Cell Gene Therapy," <i>J. Mol. Endocrinol.</i> , 11(3):335-341 (1993).
	CM	Stewart, et al., "Insulin-Releasing Pituitary Cells as a Model for Somatic Cell Gene Therapy," <i>J. Mol. Endocrinol.</i> , 143:339-343 (1994).
	CN	Suggs, et al., "Use of Synthetic Oligonucleotides as Hybridization Probes: Isolation of Cloned cDNA Sequences for Human $\beta$ 2-Microglobulin,"
	CO	Takeuchi, et al., "In Vitro Transcription and Replication of the Mumps Virus Genome," <i>Archiv. Virol.</i> , 128:177-183 (1993).
	CP	Tanabayashi, et al., "Expression of Mumps Virus Glycoproteins in Mammalian Cells from Cloned cDNA's: Both F and HN Proteins are Required for Cell Fusion," <i>Virol.</i> , 187:801-804 (1992).
	CQ	Tanabayashi, et al., "Identification of an Amino Acid that Defines the Fusogenicity of Mumps Virus," <i>J. Virol.</i> , 67:2928-2931 (1993).
J.P.	CR	Ting, et al., "Endogenous Retroviral Sequences are Required for Tissue-Specific Expression fo a Human Salivary Amylase Gland," <i>Genes Dev.</i> , 6:1457-1465 (1992).

EXAMINER

Sharon P. M.

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1.P.	CS	Tomita, et al., "A Novel Type of Human $\alpha$ -Amylase Produced in Lung Carcinoid Tumor," <i>Gene</i> , 76:11-18 (1989).
	CT	Towbin, et al., "Electrophoretic Transfer of Proteins from Polyacrylamide Gels to Nitrocellulose Sheets: Procedure and Some Applications," <i>Proc. Nat'l. Acad. Sci. USA</i> , 76:4350-4354 (1979).
	CU	Wolff, et al., "Direct Gene Transfer into Mouse Muscle In Vivo," <i>Science</i> , 247:1465-1468 (1990).
	CV	Wood, et al., "Expression of Active Human Factor VIII from Recombinant DNA Clones," <i>Nature</i> , 312:330-337 (1984).
	CW	Yang, et al., "In Vivo and In Vitro Gene Transfer to Mammalian Somatic Cells by Particle Bombardment," <i>Proc. Nat'l. Acad. Sci. USA</i> , 87:9568-9572 (1990).
	CX	Taniguchi, et al., "Constant delivery of proinsulin by encapsulation of transfected cells," <i>J. Surgical Res.</i> , 70:41-45 (1997).
	CY	Adesanya, et al., "Immediate Inflammatory Responses to Adenovirus-Mediated Gene Transfer in Rat Salivary Glands," <i>Human Gene Therapy</i> , 7:1085-1093 (June 10, 1996).
	CZ	Barka, et al., "Retrovirus-Mediated Gene Transfer into Salivary Glands In Vivo," <i>Human Gene Therapy</i> , 7:613-618 (March 20, 1996).
	DA	Buckel, et al., "Recombinant proteins for therapy," <i>TIPS</i> , 17:450 (1996).
	DB	Curiel, et al., "Gene transfer to respiratory epithelial cells via the receptor-mediated endocytosis pathway," <i>Am. J. Respir. Cell. Mol. Biol.</i> , 6(3):247-252 (1992).
	DC	Friedmann, "Human gene therapy--an immature genie, but certainly out of the bottle," <i>Nature Med.</i> , 2:144 (1996).
	DD	Geokas, et al., "Molecular forms of immunoreactive pancreatic elastase in canine pancreatic and peripheral blood," <i>Am. J. Physiol.</i> , 238:238-246 (1980).
	DE	Hahn, et al., "Phenotypic Correction of Dwarfism by Constitutive Expression of Growth Hormone," <i>Endocrinology</i> , 137(11):4988-4993 (1996).
	DF	Ishenman, et al., "Transport of $\alpha$ -Amylase Across the Basolateral Membrane of the Pancreatic Acinar Cell," <i>Proc. Nat'l Acad. Sci. U.S.A.</i> , 74(9):4068-4072 (1977).
1.P.	DG	Kagami, et al., "Evidence for the Systemic Delivery of a Transgene Product from Salivary Glands," <i>Human Gene Therapy</i> , 7:2177-2184 (Nov. 10, 1996).

EXAMINER	<i>Deana P. W.</i>	DATE CONSIDERED	<i>10/12/05</i>
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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER

*Michael Pina*

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*10/12/08*

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